

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA-HQ-OPPT-2011-0942; FRL-9333-3]

RIN 2070-AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 17 chemical substances which were the subject of premanufacture notices (PMNs). Two of these chemical substances are subject to TSCA consent orders issued by EPA. This action requires persons who intend to manufacture, import, or process any of these 17 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: This rule is effective on [insert date 60 days after date of publication in the Federal Register]. For purposes of judicial review, this rule shall be promulgated at 1

Written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs must be received on or before [insert date 30 days after date of publication in the Federal Register] (see Unit VI. of the SUPPLEMENTARY INFORMATION).

p.m. (e.s.t.) on [insert date 14 days after date of publication in the Federal Register].

For additional information on related reporting requirement dates, see Units I.A., VI., and VII. of the **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0942, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments.
- Mail: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East, Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2011-0942. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2011-0942. EPA's policy is that all comments received will be included in the docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact

information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at http://www.regulations.gov. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at http://www.regulations.gov, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject

to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances contained in this rule. Potentially affected entities may include, but are not limited to:

 Manufacturers, importers, or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

- B. What Should I Consider as I Prepare My Comments for EPA?
- 1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete

version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

- 2. Tips for preparing your comments. When submitting comments, remember to:
- i. Identify the document by docket ID number and other identifying information (subject heading, Federal Register date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
 - vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is promulgating these SNURs using direct final procedures. These SNURs will require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of a chemical substance for any activity designated by these SNURs as a significant new use. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** issue of April 24, 1990 (55 FR 17376) (April 24, 1990 SNUR). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

• The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 17 chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to this Rule

EPA is establishing significant new use and recordkeeping requirements for 17 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) consent order or, for non-section 5(e) SNURs, (i.e., SNURs without TSCA section 5(e) consent orders), the basis for the SNUR.
 - Toxicity concerns.
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
 - CFR citation assigned in the regulatory text section of this rule.

The regulatory text section of this rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (i.e., limits on manufacture and importation volume) and other uses designated in this rule, may be claimed as CBI. Unit IX. discusses a procedure companies may use to ascertain whether a proposed use constitutes a significant new use.

This rule includes two PMN substances (P-10-486 and P-10-487) that are subject to "risk-based" consent orders under TSCA section 5(e)(1)(A)(ii)(I) in which EPA determined that activities associated with the PMN substances may present unreasonable risk to human health or the environment. Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called "5(e) SNURs" on these PMN substances are promulgated pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The 5(e) SNURs designate as a "significant new use" the absence of the protective measures required in the corresponding consent orders.

This rule also includes SNURs on 15 PMN substances (P-09-248, P-11-33, P-11-34, P-11-188, P-11-316, P-11-333, P-11-424, P-11-511, P-11-546, P-11-578, P-11-580, P-11-591, P-11-608, P-11-637, and P-11-662) that are not subject to consent orders under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a "significant new use." These so-called "non-5(e) SNURs" are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a "significant new use" in all non-5(e)

SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, "(i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified" for the PMN substance.

PMN Number P-09-248

Chemical name: Ethyleneamine polyphosphates (generic).

CAS number: Not available.

Basis for action: The PMN states that the use of the substance will be as a flame retardant added to polymers. Based on test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur if releases of the PMN substance to surface water from uses other than described in the PMN exceed the releases expected from the use described in the PMN. For the described use in the PMN, significant environmental releases are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as described in the PMN may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(i).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10282.

PMN Numbers P-10-486 and P-10-487

Chemical names: (P-10-486) Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-sulfo-.omega.hydroxy-, C12-13-branched and linear alkyl ethers, sodium salts and (P-10-487) Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-sulfo-.omega.-hydroxy-, C14-15-branched and linear alkyl ethers, sodium salts.

CAS numbers: (P-10-486) 958238-81-8 and (P-10-487) 958238-82-9.

Effective date of TSCA section 5(e) consent order: July 22, 2011.

Basis for TSCA section 5(e) consent order: The PMNs state that the use of the substances will be for downhole injection for enhanced oil recovery. The order was issued under TSCA sections 5(e)(1)(A)(i), (e)(1)(A)(ii)(I), and (e)(1)(A)(ii)(II) based on a finding that these substances may present an unreasonable risk of injury to the environment and will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities. To protect against the risk, the order requires certain hazard communication requirements, specific disposal requirements for processing and use, and prohibits releases from manufacture of the PMN substances resulting in surface water concentrations exceeding 28 parts per billion (ppb) for P-10-486 and 4 ppb for P-10-487. The SNUR designates as a "significant new use" the absence of these protective measures.

Toxicity concern: Based on ecological structure activity relationship (EcoSAR) analysis of test data on analogous anionic surfactants, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 28 ppb for P-10-486 and 4 ppb for P-10-487 in surface waters.

Recommended testing: EPA has determined that the results of a fish acute toxicity test (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) on P-10-487 would help characterize the environmental effects of the PMN substances. The PMN submitter agreed not to exceed the production volume limit in the consent order before conducting these tests.

CFR citations: 40 CFR 721.10283 (P-10-486) and 40 CFR 721.10284 (P-10-487).

PMN Number P-11-33

Chemical name: Formaldehyde, polymer with 4-(1,1-dimethylethyl)phenol, reaction products with 1-piperazineethanamine.

CAS number: 1191244-16-2.

Basis for action: The PMN states that the PMN substance will be used as a hardener for epoxy resin laminating systems. Based on ecological structure activity relationship (EcoSAR) analysis of test data on analogous aliphatic amines and phenol-amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 17 ppb of the PMN substance in surface waters. As described in the PMN, the substance is not released to surface waters. Therefore, EPA has not determined that the proposed manufacture, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 17 ppb may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test. freshwater (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10285.

PMN Number P-11-34

Chemical name: Formaldehyde, polymer with .alpha.-(2-aminomethylethyl)-.omega.-(2aminomethylethoxy)poly[oxy(methyl-1,2-ethanediyl)] and 4-(1,1-dimethylethyl)phenol. *CAS number:* 1192146-78-3.

Basis for action: The PMN states that the PMN substance will be used as a hardener for epoxy resin laminating systems. Based on EcoSAR analysis of test data on analogous aliphatic amines and phenol-amines, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 21 ppb of the PMN substance in surface waters. As described in the PMNs, the substances are not released to surface waters. Therefore, EPA has not determined that the proposed manufacture, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 21 ppb may cause significant adverse environmental effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I

and II (OPPTS Test Guideline 850.5400) would help characterize the environmental

effects of the PMN substance.

CFR citation: 40 CFR 721.10286.

PMN Number P-11-188

Chemical name: Infused carbon nanostructures (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance

is as an additive to provide conductive properties to reinforcements used in composites.

Based on available information on analogous chemical substances, the PMN substance

may cause lung effects. For the use described in the PMN, no significant inhalation

exposures are expected. Therefore, EPA has not determined that the proposed

manufacturing, processing, or use of the substance may present an unreasonable risk.

EPA has determined, however, that a manufacturing process other than as described in

the PMN (the manufacturing process described in the PMN includes incorporation of the

PMN substance into pellets) may cause serious health effects. Based on this information,

the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of the following information

would help characterize the health effects of the PMN substance: The dimensions,

characteristics, and physical-chemical properties of the carbon nanostructures. These

properties should be determined once a year for three consecutive years.

CFR citation: 40 CFR 721.10287.

PMN Number P-11-316

Chemical name: Cyclohexane, oxidized, by-products from, distn. residues.

CAS number: 1014979-92-0.

Basis for action: The PMN states that the generic (non-confidential) uses of the substance

are as an industrial solvent in closed and open systems, and as an accelerant in permitted

industrial explosives. Based on EcoSAR analysis of test data on analogous esters, EPA

predicts toxicity to aquatic organisms may occur at concentrations that exceed 4 ppb of

the PMN substance in surface waters. As described in the PMN, the substance is not

released to surface waters. Therefore, EPA has not determined that the proposed

manufacturing, processing, or use of the substance may present an unreasonable risk.

EPA has determined, however, that any use of the substance resulting in surface water

concentrations exceeding 4 ppb may cause significant adverse environmental effects.

Based on this information, the PMN substance meets the concern criteria at

§ 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test,

freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute

toxicity test, fresh water daphnids (OPPTS Test Guideline 850.1010); and an algal

toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the

environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10288.

PMN Number P-11-333

Chemical name: Hexanedioic acid polymer with aliphatic polyol dihydrogen phosphate

aromatic ester (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use will be as a

component of industrial coatings. Based on EcoSAR analysis of test data on analogous

organic phosphates, EPA predicts toxicity to aquatic organisms may occur if releases of

the PMN substance to surface water from uses other than described in the PMN exceed

the releases expected from the use described in the PMN. For the described use in the

PMN, significant environmental releases are not expected. Therefore, EPA has not

determined that the proposed manufacturing, processing, or use of the substance may

present an unreasonable risk. EPA has determined, however, that any use of the substance

other than as described in the PMN may cause significant adverse environmental effects.

Based on this information, the PMN substance meets the concern criteria at §

721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a ready biodegradability

test (OPPTS Test Guideline 835.3110); a fish early-life stage toxicity test (OPPTS Test

Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300);

and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help

characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10289.

PMN Number P-11-424

Chemical name: Alkenoyloxy arylphenone (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance

is as a monomer for polymer applications. Based on test data on the PMN substance, and

EcoSAR analysis of test data on analogous methacrylates, EPA predicts toxicity to

aquatic organisms may occur at concentrations that exceed 26 ppb of the PMN substance in surface waters. As described in the PMN, releases to surface waters are not expected to exceed 26 ppb. Therefore, EPA has not determined that the proposed manufacture, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 26 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(4)(i) and (b)(4)(ii).

Recommended testing: EPA has determined that the results a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400) and a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10290.

PMN Number P-11-511

Chemical name: C15 olefins (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a petroleum substitute base. Based on EcoSAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, the substance is not released to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance

resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance.

**CFR citation: 40 CFR 721.10291.

PMN Number P-11-546

Chemical name: Silicate (2-), hexafluoro-, cesium (1:2).

CAS number: 16923-87-8.

Basis for action: The PMN states that the PMN substance will be used as a brazing (metal joining) agent. Based on submitted test data for an analogous PMN substance, EPA identified concerns for degeneration of the kidneys, necrosis of the heart muscle, and effects on the male reproductive organs to workers from inhalation exposure to the PMN substance. For the uses described in the PMN, significant dermal or inhalation exposure is not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, use of the substance other than as a brazing (metal joining) agent may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a repeated dose 28-day oral toxicity test (OPPTS Test Guideline 870.3050) in rodents would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10292.

PMN Number P-11-578

Chemical name: Benzoic acid, 4-(1,1-dimethylethyl)-, hydrazide.

CAS number: 43100-38-5.

Basis for action: The PMN states that the use of this substance will be as an intermediate.

Based on SAR analysis of test data on analogous hydrazines, EPA identified concerns for

mutagenicity, oncogenicity, developmental toxicity, dermal sensitization, and respiratory

sensitization from exposure to the PMN substance via the inhalation route. In addition,

based on EcoSAR analysis of analogous hydrazines, EPA predicts toxicity to aquatic

organisms may occur at concentrations that exceed 2 ppb of the PMN substance in

surface waters. For the intermediate use described in the PMN, inhalation exposures and

environmental releases to surface waters are not expected. Therefore, EPA has not

determined that the proposed manufacturing, processing, or use of the substance may

present an unreasonable risk. EPA has determined, however, that any use of the substance

other than as an intermediate, or any use resulting in surface water concentrations

exceeding 2 ppb may cause serious health effects and significant adverse environmental

effects. Based on this information, the PMN substance meets the concern criteria at §

721.170 (b)(1)(i)(C), (b)(3)(ii), and (b)(4)(ii).

Recommended testing: EPA has determined that the results of a 90-day oral toxicity test in rodents (OPPTS Test Guideline 870.3100) by the inhalation route; a carcinogenicity

test (OPPTS Test Guideline 870.4200) by the inhalation route, in two species of rodents; a fish acute toxicity test (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the human health and environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10293.

PMN Number P-11-580

Chemical name: Cyclohexanol, 2,6-bis(1,1-dimethylethyl)-4-methyl-.

CAS number: 163119-16-2.

Basis for action: The PMN states that the use of this substance will be as an intermediate. Based on EcoSAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters. As described in the PMN, releases to surface waters are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has

determined, however, that any use resulting in surface water concentrations exceeding 2 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10294.

PMN Number P-11-591

Chemical name: IPDI modified isophthalic acid, neopentyl glycol and adipic acid

(generic).

CAS numbers: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance

will be as a lamination adhesive. Based on test data on analogous substances, EPA

identified concerns for oncogenicity, if the PMN substance is inhaled, as well as concerns

for irritation to the eyes, skin, mucous membranes, and dermal and respiratory

sensitization to workers from dermal and inhalation exposure to the PMN. For the

industrial uses described in the PMN, and due to the use of personal protective

equipment, significant worker exposure is unlikely, as dermal or inhalation exposure is

not expected. Therefore, EPA has not determined that the proposed manufacturing,

processing, or use of this substance may present an unreasonable risk. EPA has

determined, however, that substantial production volume increases, or use of the

substance in consumer products may cause serious health effects. Based on this

information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C) and

(b)(3)(ii).

Recommended testing: EPA has determined that the results of a dermal sensitization test

(OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test

Guideline 870.3465) would help characterize the human health effects of the PMN

substance.

CFR citation: 40 CFR 721.10295.

PMN Number P-11-608

Chemical name: 1,3-Benzenediol, 4-[1-[[3-(IH-imidazol-1-yl)propyl]imino]ethyl]-.

CAS number: 1313999-39-1.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an epoxy catalyst. Based on EcoSAR analysis of test data on polycationic polymers, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, the substance is not released to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test, tiers I and II (OPPTS Test Guideline 850.5400) would help characterize the environmental effects of the PMN substance. Additionally, EPA recommends that OPPTS Test Guideline 850.1000, "Special Considerations for Conducting Aquatic Laboratory Studies" be consulted for materials, such as this PMN substance, that are water insoluble or of low water solubility.

CFR citation: 40 CFR 721.10296.

PMN Number P-11-637

Chemical name: Tin, C16-18 and C18-unsatd. fatty acids castor-oil fatty acids

complexes.

CAS number: 1315588-63-6.

Basis for action: The PMN states that the use of the substance will be as a polyurethane

foam catalyst. Based on test data on the PMN substance, EPA identified concerns for

dermal sensitization and blood and liver toxicity to workers from exposure to the PMN

substance. For the industrial use described in the PMN, and due to the use of personal

protective equipment, significant worker exposure is unlikely, as dermal or inhalation

exposure is not expected. Therefore, EPA has not determined that the proposed

manufacturing, processing, or use of this substance may present an unreasonable risk.

EPA has determined, however, that domestic manufacture of the substance or use of the

substance in consumer products may cause serious health effects. Based on this

information, the PMN substance meets the concern criteria at § 721.170(b)(3)(i).

Recommended testing: EPA has determined that the results of a 28-day dermal toxicity

study (OPPTS Test Guideline 870.3200) would help characterize the human health

effects of the PMN substance.

CFR citation: 40 CFR 721.10297.

PMN Number P-11-662

Chemical name: MDI terminated polyester polyurethane polymer (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance

will be as a liquid moisture cure adhesive. Based on test data on analogous diisocyanates,

EPA identified concerns for mutagenicity, irritation to lungs and mucous membranes, and dermal and respiratory sensitization to workers from dermal and inhalation exposure to the PMN substance. For the industrial uses described in the PMN, and due to the use of personal protective equipment, significant worker exposure is unlikely, as dermal or inhalation exposure is not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance in consumer products may cause serious health effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a dermal sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10298.

V. Rationale and Objectives of the Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these SNURs, EPA concluded that for two of the 17 chemical substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The SNUR provisions for these

chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are promulgated pursuant to § 721.160 (see Unit II.).

In the other 15 cases, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

B. Objectives

EPA is issuing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this rule:

- EPA will receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for the described significant new use.
- EPA will be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA will ensure that all manufacturers, importers, and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html.

VI. Direct Final Procedures

EPA is issuing these SNURs as a direct final rule, as described in § 721.160(c)(3) and § 721.170(d)(4). In accordance with § 721.160(c)(3)(ii) and § 721.170(d)(4)(i)(B), the effective date of this rule is [insert date 60 days after date of publication in the Federal Register] without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before [insert date 30 days after date of publication in the Federal Register].

If EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments, on one or more of these SNURs before [insert date 30 days after date of publication in the Federal Register], EPA will withdraw the relevant sections of this direct final rule before its effective date. EPA will then issue a proposed SNUR for the chemical substance(s) on which adverse or critical comments were received, providing a 30-day period for public comment.

This rule establishes SNURs for a number of chemical substances. Any person who submits adverse or critical comments, or notice of intent to submit adverse or critical comments, must identify the chemical substance and the new use to which it applies.

EPA will not withdraw a SNUR for a chemical substance not identified in the comment.

VII. Applicability of Rule to Uses Occurring Before Effective Date of the Rule

Significant new use designations for a chemical substance are legally established as of the date of publication of this direct final rule, [insert date of publication in the Federal Register].

To establish a significant "new" use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. TSCA section 5(e) consent orders have been issued for two chemical substances and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which EPA is designating as significant new uses. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no other person may commence such activities without first submitting a PMN. For chemical substances for which an NOC has not been submitted at this time, EPA concludes that the uses are not ongoing. However, EPA recognizes that prior to the effective date of the rule, when chemical substances identified in this SNUR are added to the TSCA Inventory, other persons may engage in a significant new use as defined in this rule before the effective date of the rule. However, 7 of the 17 chemical substances contained in this rule have CBI chemical identities, and since EPA has received a limited number of post-PMN bona fide submissions (per §§ 720.25 and 721.11), the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

As discussed in the April 24, 1990 SNUR, EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of this direct final rule rather than as of the effective date of the

rule. If uses begun after publication were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements because a person could defeat the SNUR by initiating the significant new use before the rule became effective, and then argue that the use was ongoing before the effective date of the rule. Thus, persons who begin commercial manufacture, import, or processing of the chemical substances regulated through this SNUR will have to cease any such activity before the effective date of this rule. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

EPA has promulgated provisions to allow persons to comply with this SNUR before the effective date. If a person meets the conditions of advance compliance under § 721.45(h), the person is considered exempt from the requirements of the SNUR.

VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. The two exceptions are:

- 1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
- 2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the

authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for non-5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the harmonized test guidelines referenced in this document electronically, please go to http://www.epa.gov/ocspp and select "Test Methods and Guidelines."

In the TSCA section 5(e) consent orders for two of the chemical substances regulated under this rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study at least 14 weeks (earlier TSCA section 5(e) consent orders required submissions at least 12 weeks) before reaching the specified production limit. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture, import, or processing.

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
 - Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. Procedural Determinations

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at 40 CFR 721.1725(b)(1).

Under these procedures a manufacturer, importer, or processor may request EPA to determine whether a proposed use would be a significant new use under the rule. The manufacturer, importer, or processor must show that it has a *bona fide* intent to

manufacture, import, or process the chemical substance and must identify the specific use for which it intends to manufacture, import, or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture, import, or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers, importers, and processors can combine the *bona fide* submission under the procedure in § 721.1725(b)(1) with that under § 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, i.e., the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture, import, or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

X. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in §

720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 721.25 and 720.40. E-PMN software is available electronically at http://www.epa.gov/opptintr/newchems.

XI. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2011-0942.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866

This rule establishes SNURs for several new chemical substances that were the subject of PMNs, or TSCA section 5(e) consent orders. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the

OMB approval number for the information collection requirements contained in this rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act

On February 18, 2012, EPA certified pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true: (1) A significant number of SNUNs would not be submitted by small entities in response to the SNUR, and (2) the SNUN submitted by any small entity would not cost significantly more than \$8,300. A copy of that certification is available in the docket for this rule.

This rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit XI and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true: (1) A significant number of SNUNs would not be submitted by small entities in response to the SNUR and (2) submission of the SNUN would not cost any small entity significantly more than \$8,300. Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this rule. As such, EPA has determined that this rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any affect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

E. Executive Order 13132

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This rule does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This action is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution,

or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

In addition, since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), does not apply to this action. *J. Executive Order 12898*

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

XIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

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List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: March 23, 2012.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR parts 9 and 721 are amended as follows:

PART 9--[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 et seq., 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 et seq., 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 et seq., 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. The table in § 9.1 is amended by adding the following sections in numerical order under the undesignated center heading "Significant New Uses of Chemical Substances" to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation			OMB control No.				
*	*	*	*	*			
Significant New Uses of Chemical Substances							
*	*	*	*	*			
721.10282			2070-0012				
721.10283			2070-0012				
721.10284			2070-0012				
721.10285			2070-0012				
721.10286			2070-0012				

721.10287			2070-0012	
721.10288			2070-0012	
721.10289			2070-0012	
721.10290			2070-0012	
721.10291			2070-0012	
721.10292			2070-0012	
721.10293			2070-0012	
721.10294			2070-0012	
721.10295			2070-0012	
721.10296			2070-0012	
721.10297			2070-0012	
721.10298			2070-0012	
*	*	*	*	*

* * * * * *

PART 721--[AMENDED]

3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

4. Add § 721.10282 to subpart E to read as follows:

§ 721.10282 Ethyleneamine polyphosphates (generic).

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as ethyleneamine polyphosphates (PMN P-09-248) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
 - 5. Add § 721.10283 to subpart E to read as follows:
- § 721.10283 Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-sulfo-.omega.-hydroxy-, C12-13-branched and linear alkyl ethers, sodium salts.
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as poly[oxy(methyl-1,2-ethanediyl)], .alpha.-sulfo-.omega.-hydroxy-, C12-13-branched and linear alkyl ethers, sodium salts (PMN P-10-486; CAS No. 958238-81-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Hazard communication program*. Requirements as specified in § 721.72 (a), (b), (c), (d), (f), (g)(3)(i), (g)(3)(ii), (g)(4)(i), (g)(4)(ii), (g)(4)(iii), and (g)(5).

- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(p) (330,000 kilograms for this substance and P-10-487 combined)
- (iii) *Disposal*. Requirements as specified in § 721.85 (b)(1) and (c)(1) solvent rinsate resulting from cleaning of storage and holding tanks, shipboard tanks, iso containers, rail cars, and trucks used to transport the substance may only be disposed of by incineration. Sampling wastes containing the substance may only be disposed of by incineration, and § 721.85(c)(3) for oilfield applications, when the substance will no longer be injected into a well at a particular site for enhanced oil recovery, the water rinsate of the field holding tank and any remaining field water containing the substance must be injected into a designated disposal well, either a class I hazardous waste disposal well or another class II well.
 - (iv) Release to water. Requirements as specified in $\S 721.90(a)(4)$ (N = 28).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (f), (g), (h), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this significant new use rule.
 - 6. Add § 721.10284 to subpart E to read as follows:
- § 721.10284 Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-sulfo-.omega.-hydroxy-, C14-15-branched and linear alkyl ethers, sodium salts.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as poly[oxy(methyl-1,2-ethanediyl)], .alpha.-sulfo-.omega.-hydroxy-, C14-15-branched and linear alkyl ethers, sodium salts (PMN P-10-487; CAS No. 958238-82-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Hazard communication program*. Requirements as specified in § 721.72 (a), (b), (c), (d), (f), (g)(3)(i), (g)(3)(ii), (g)(4)(i), (g)(4)(ii), (g)(4)(iii), and (g)(5).
- (ii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80 (p) (330,000 kilograms for this substance and for P-10-486 combined)
- (iii) *Disposal*. Requirements as specified in § 721.85 (b)(1) and (c)(1) solvent rinsate resulting from cleaning of storage and holding tanks, shipboard tanks, iso containers, rail cars, and trucks used to transport the substance may only be disposed of by incineration. Sampling wastes containing the substance may only be disposed of by incineration, and § 721.85(c)(3) for oilfield applications, when the substance will no longer be injected into a well at a particular site for enhanced oil recovery, the water rinsate of the field holding tank and any remaining field water containing the substance must be injected into a designated disposal well, either a class I hazardous waste disposal well or another class II well.
 - (iv) Release to water. Requirements as specified in $\S 721.90(a)(4)$ (N = 4).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (f), (g), (h), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this significant new use rule.
 - 7. Add § 721.10285 to subpart E to read as follows:

§ 721.10285 Formaldehyde, polymer with 4-(1,1-dimethylethyl)phenol, reaction products with 1-piperazineethanamine.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as formaldehyde, polymer with 4-(1,1-dimethylethyl)phenol, reaction products with 1-piperazineethanamine (PMN P-11-33; CAS No. 1191244-16-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=17 parts per billion (ppb)).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

- 8. Add § 721.10286 to subpart E to read as follows:
- § 721.10286 Formaldehyde, polymer with .alpha.-(2-aminomethylethyl)-.omega.-(2-aminomethylethoxy)poly[oxy(methyl-1,2-ethanediyl)] and 4-(1,1-dimethylethyl)phenol.
- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as formaldehyde, polymer with .alpha.-(2-aminomethylethyl)-.omega.-(2-aminomethylethoxy)poly[oxy(methyl-1,2-ethanediyl)] and 4-(1,1-dimethylethyl)phenol) (PMN P-11-34; CAS No. 1192146-78-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=21 ppb).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
 - 9. Add § 721.10287 to subpart E to read as follows:
- § 721.10287 Infused carbon nanostructures (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as infused carbon nanostructures (PMN P-11-188) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j) (manufacturing process described in the PMN; the process described in the PMN includes the incorporation of the PMN substance into pellets).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c) and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this significant new use rule.
 - 10. Add § 721.10288 to subpart E to read as follows:

§ 721.10288 Cyclohexane, oxidized, by-products from, distn. residues.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as cyclohexane, oxidized, by-products from, distn. residues (PMN P-11-316; CAS No. 1014979-92-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:

- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=4 ppb).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this significant new use rule.
 - 11. Add § 721.10289 to subpart E to read as follows:

§ 721.10289 Hexanedioic acid polymer with aliphatic polyol dihydrogen phosphate aromatic ester (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as hexanedioic acid polymer with aliphatic polyol dihydrogen phosphate aromatic ester (PMN P-11-333) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(j).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.
- (3) Determining whether a specific use is subject to this section. The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.
 - 12. Add § 721.10290 to subpart E to read as follows:

§ 721.10290 Alkenoyloxy arylphenone (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as alkenoyloxy arylphenone (PMN P-11-424) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=26).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

13. Add § 721.10291 to subpart E to read as follows:

§ 721.10291 C15 olefins (generic).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified generically as C15 olefins (PMN P-11-511) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1 ppb).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 14. Add § 721.10292 to subpart E to read as follows:

§ 721.10292 Silicate (2-), hexafluoro-, cesium (1:2).

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as silicate (2-) hexafluoro-cesium (1:2) (PMN P-11-546; CAS No. 16923-87-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:

- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80 (j) (use as brazing (metal joining) agent).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 15. Add § 721.10293 to subpart E to read as follows:

§ 721.10293 Benzoic acid, 4-(1,1-dimethylethyl)-, hydrazide.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as benzoic acid, 4-(1,1-dimethylethyl)-, hydrazide (PMN P-11-578; CAS No. 43100-38-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(g).
- (ii) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=2 ppb).
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 16. Add § 721.10294 to subpart E to read as follows:

§ 721.10294 Cyclohexanol, 2,6-bis(1,1-dimethylethyl)-4-methyl-.

- (a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as cyclohexanol, 2,6-bis(1,1-dimethylethyl)-4-methyl-(PMN P-11-580; CAS No. 163119-16-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=2 ppb).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) Limitations or revocation of certain notification requirements. The provisions of § 721.185 apply to this section.

17. Add new § 721.10295 to subpart E to read as follows:

§ 721.10295 IPDI modified isophthalic acid, neopentyl glycol and adipic acid (generic).

- (a) Chemical substances and significant new uses subject to reporting. (1) The chemical substance identified generically as IPDI modified isophthalic acid, neopentyl glycol and adipic acid (PMN P-11-591) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80 (o) and (s) (15,000 kilograms).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 18. Add new § 721.10296 to subpart E to read as follows:

§ 721.10296 1,3-Benzenediol, 4-[1-[[3-(IH-imidazol-1-yl)propyl]imino] ethyl]-.

(a) Chemical substance and significant new uses subject to reporting. (1) The chemical substance identified as 1,3-benzenediol, 4-[1-[[3-(lH-imidazol-1-yl)propyl]imino[ethyl]- (PMN P-11-608; CAS No. 1313999-39-1) is subject to reporting

under this section for the significant new uses described in paragraph (a)(2) of this section.

- (2) The significant new uses are:
- (i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1 ppb).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (k) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 19. Add new § 721.10297 to subpart E to read as follows:

§ 721.10297 Tin, C16-18 and C18-unsatd. fatty acids castor-oil fatty acids complexes.

- (a) Chemical substances and significant new uses subject to reporting. (1) The chemical substance identified as tin, C16-18 and C18-unsatd. fatty acids castor-oil fatty acids complexes (PMN P-11-637; CAS No. 1315588-63-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80 (f) and (o).
 - (ii) [Reserved]

- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.
 - 20. Add new § 721.10298 to subpart E to read as follows:

§ 721.10298 MDI terminated polyester polyurethane polymer (generic).

- (a) Chemical substances and significant new uses subject to reporting. (1) The chemical substance identified generically as MDI terminated polyester polyurethane polymer (P-11-662) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.
 - (2) The significant new uses are:
- (i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(o).
 - (ii) [Reserved]
- (b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.
- (1) Recordkeeping. Recordkeeping requirements as specified in § 721.125 (a), (b),(c), and (i) are applicable to manufacturers, importers, and processors of this substance.
- (2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

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